

- 1) An assay test that comprises a single device so that it is easy to use. In preferred embodiments, the assay test is also small, fast, accurate, inexpensive, safe, easy to read and decipher, and durable; and
- 2) A delivery system that stores multiple assay tests so that the assay tests can be accessed on one or more occasions. In preferred embodiments, the delivery system makes assay tests both easy to carry and durable. In some preferred embodiments, the delivery system comprises a protective storage container providing a cap with an air tight seal and a plug, sleeve, pouch, liner, or other material comprising an entrained desiccant that removes moisture away from the contents of the container. In other preferred embodiments, the delivery system comprises a folded structure, wherein assays test are attached or enclosed in an interior portion of the folded structure. In preferred embodiments, the delivery system is small and portable to allow ease of handling.

Preferred embodiments of the present invention provide tests and systems that facilitate wide-spread use of assay tests by individuals. For example, the present invention provides assay tests that are contained within a single device and are easy to use, small, fast, accurate, reliable, inexpensive, easy to read and decipher and durable. In preferred embodiments, multiple tests are contained in a delivery system such that one or more tests can be accessed and used at separate times.

Thus, in some embodiments, the assay test of the present invention comprises a single device so that it is easy to use. In preferred embodiments, the assay test is small so that it is easy to carry. In some preferred embodiments, the assay test works fast so people do not have to wait long before obtaining the results. In other preferred embodiments, the assay test is accurate so individuals can make decisions based on correct information. In yet other preferred embodiments, the assay test is reliable so people know when it is functioning properly. In some embodiments, reliability is provided by assay tests that have undergone sufficient quality control and assessment to provide highly accurate and consistent results. In some embodiments, the assay test

includes an indicator to identify, upon use, if the test is reliable. In some preferred embodiments, the assay test is inexpensive so that it can be afforded easily. In still other preferred embodiments, the assay test is durable so that it can be handled easily without breaking or becoming damaged. Unlike currently available detection devices, the assay tests of the present invention combine these desired features into a single, easy to use test that significantly facilitates self-detection and assessment of analytes.

The present invention further provides delivery systems that a) store multiple assay tests so that they can be accessed on one or more occasions (e.g., on one or more separate days, weeks, or months), b) in some embodiments, make assay tests durable and easy to access and carry, and c) in some other embodiments, provide placards for instructions, warnings, labels, and other text or diagrams. As mentioned above, the delivery systems of the present invention store multiple assay tests so that multiple assay tests can be accessed on a single occasion or on two or more distinct occasions. This flexibility is important for several reasons. For example, because individuals may use assay tests on separate occasions, the delivery system stores a sufficient quantity of tests to last an individual a period of days, weeks or months, thereby diminishing the need to continually replenish assay test supply. Additionally, because individuals may use more than one tests on a given occasion, for example, to determine if their analyte concentration has dropped over time, the delivery system stores multiple assay tests.

In preferred embodiments of the present invention, the delivery system makes assay tests easy to carry so that individuals can easily and discreetly put the assay tests in their pockets, wallets, or purses for use in situations away from home. In other preferred embodiments, the delivery system ensures the durability of the assay tests by enclosing them in a protective hard container. In some preferred embodiments, the container comprises a plastic-polymer container with an entrained desiccant. Such a protective container assures that the assay tests do not break or spoil due to a breakdown or degradation of the biosensor, enzymes, antibodies, antigens, colorimetric agents, or other reaction agents. In yet other preferred embodiments, the delivery system makes assay tests easy to access so that removal of the assay test from the

delivery system can be conveniently accomplished, even by impaired individuals. Thus, in some embodiments of the present invention, an assay test is dispensed upon opening the delivery system, while the remaining tests are maintained in the delivery system (*e.g.*, maintained so as not to be exposed to the environment). In some preferred embodiments, the delivery system provides large placards so that instructions, labels, warnings, or other text or diagrams are easy to notice and read. The assay tests, first package, or second package may also contain such information.

The present invention further contemplates assay tests and delivery systems that provide advantages for distribution of the tests and systems to individual consumers by one or more secondary parties (*i.e.*, parties other than the consumer). For example, it is contemplated that the assay tests are provided to consumers by another party (*e.g.*, a restaurant, bar, university, insurance company, employer, government agency, etc.). In such embodiments, it is contemplated that multiple assay tests are provided to the consumer so that testing can occur on more than one occasion to avoid distribution each time the consumer needs the test. Thus, in some embodiments of the present invention, it is desired to have delivery systems comprising multiple assay tests that can be accessed on one or more occasions. In other embodiments, it is desired to have a protective container made of a thermoplastic polymer with an entrained desiccant such that excess moisture is removed from the tests contained therein.

In some embodiments of the present invention, materials other than the assay tests are further included in or on the delivery systems. For example, in some embodiments, the delivery system or assay test comprises an image or text associated with a company, agency, or individual other than the provider of the assay test in order to obtain the positive image associated with the assay tests of the present invention (*i.e.*, co-branding). The co-branding may be provided on the surface or interior of the delivery systems, may be included on materials attached to the delivery system, or may otherwise be associated with the delivery system. In embodiments of the present invention where multiple assay tests are provided in a delivery system for use over a period of time, the co-branding provides constant and long-term advertising